

Attorney Docket No.: KBI-0017  
Inventors: Ranganathan, Natarajan  
Serial No.: 10/676,622  
Filing Date: September 30, 2003  
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#### REMARKS

Claims 1-3 are pending in the instant application. Claims 1 and 3 have been rejected. Claim 2 has been objected to. Claims 1 and 2 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### I. Rejection of Claims under 35 U.S.C. §102

Claim 1 has been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Nos. 5,733,568 and 5,032,399. It is suggested that these references teach probiotic lactic acid bacteria which are enterically coated to facilitate absorption in the intestines.

Claims 1 and 3 have been rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (U.S. Patent No. 6,080,401). It is suggested that Reddy et al. teach compositions comprising enterically-coated probiotics wherein the bacteria is *L. sporogenes*.

Applicant respectfully traverses these rejections

At the outset, neither U.S. Patent No. 5,032,399 nor U.S. Patent No. 6,080,401 fairly teach or suggest enteric coating. The '399 patent teaches using *L. acidophilus* strains in lyophilized form or in conjunction with a pharmaceutically acceptable carrier substance (see column 5, lines 53-56). Similarly the '401 patent teaches mere encapsulation at column 12 (lines 55-67) and throughout the examples with no teaching or suggestion of enteric coating. As disclosed in the specification at the paragraph bridging pages 11 and 12, enteric coating is distinct from encapsulation in that enteric coating delivers the bacterium to

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the ileal or colonic regions with coating disintegration occurring at a pH of 7.5 or higher. Accordingly, the '399 and '401 patents fail to teach or suggest all the claim limitations and therefore fail to anticipate the instant invention.

Moreover, U.S. Patent No. 5,733,568 teaches microencapsulated Lactobacilli for treating antiobiotic associated or other chronic or acute diarrhea. In contrast, the present specification teaches bacterial compositions for treatment of renal failure. In this regard, page 11 (lines 15-24) teaches that compositions containing a selected bacteria in combination with a sorbent can alleviate uremia or renal dysfunction. In accord with the teachings of the present application, specific sorbents include aluminum hydroxide gel, calcium carbonate, calcium acetate, magnesium hydroxide gel, psyllium fibers, naturally occurring gums or modified starches. The '568 patent neither teaches nor suggests such sorbents for use in combination with a selected bacterium in an enterically coated form. Thus, in an earnest effort to clarify the instant composition, Applicant has amended claim 1 to indicate that the claimed composition comprises a sorbent and a selected bacterium for treating renal failure. Because the '568 patent fails to teach or suggest all the claim limitations, this references fails to anticipate the instant invention. It is therefore respectfully requested that the rejections under U.S.C. 102(e) be reconsidered and withdrawn.

## **II. Objection to Claims**

Claim 2 has been objected to for being dependent upon a rejected base claim. It is acknowledged that claim 2 would be

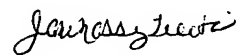
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allowable if rewritten in independent form including all the limitations of the base claim. Applicant has made the appropriate amendment to claim 2, thereby placing it in independent form. Withdrawal of this objection and allowance of this claim is respectfully requested.

### III. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata  
Registration No. 32,257

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Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515